K082039

510(K) Summary

MAR 20 2009

Submitter:

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Contact:

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Date Summary Prepared:

March 19th, 2009

Device Trade Name:

Synchro HP Platform

Common Name:

Medical Laser and Pulsed Light System

Classification Name:

Instrument, surgical, powered, laser
79-GEX
21 CFR 878.4810

Equivalent Devices:

K033172 - Candela Gentle YAG Family of Lasers
K051442 - Cynosure Photosilk Plus Pulsed Light & Laser Attachments
K072564 - Alma Lasers Harmony XL Multi-Application Platform

Device Description:

The Synchro HP Platform laser and pulsed light system is equipped with a long pulse Nd:YAG laser (1064 nm), several hand held pulsed light sources (400-950 nm), a hand-held Er:YAG laser source (2940 nm) and a hand-held Q-switched Nd:YAG laser source (1064 nm).
Emission activation is either by footswitch or finger switch.
Overall weight of the system is 170 kg.
Size is 115x53x106 cm (HxWxD).
Electrical requirement is: 230VAC, 32A, 50-60 Hz, single phase.

Indications for Use:

The Synchro HP Platform laser and pulsed light system is indicated for the following treatments:

Nd:YAG Laser (1064 nm): removal of unwanted hair, for stable long term or permanent hair reduction (Skin Types Fitzpatrick I-VI), photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to warts, teleangiectasia, leg veins and spider veins, treatment of benign pigmented lesions.

Er:YAG Laser attachment (2940 nm): skin resurfacing and incision, excision, ablation or vaporization of soft bodily tissues.

Indications for Use (continued):

Q-switched Nd:YAG Laser attachment (1064 nm): removal of dark tattoos and treatment of benign pigmented lesions.

Pulsed Light attachments (400, 500, 520, 550, 650 to 950 nm): permanent hair reduction, treatment of benign cutaneous vascular lesions including facial and leg veins, benign pigmented epidermal lesions, moderate inflammatory acne vulgaris.

400-950 nm Pulsed Light attachment:
- ✓ Moderate Inflammatory Acne Vulgaris (skin types I, II, III, IV)

500-950 nm Pulsed Light attachment:
- ✓ Benign Cutaneous Vascular Lesions (skin types I, II)

520-950 nm Pulsed Light attachment:
- ✓ Benign Cutaneous Vascular Lesions (skin type III)
- ✓ Benign Pigmented Epidermal Lesions (skin types I, II)
- ✓ Permanent Hair Reduction (skin types I, II)

550-950 nm Pulsed Light attachment:
- ✓ Benign Pigmented Epidermal Lesions (skin types III, IV)
- ✓ Permanent Hair Reduction (skin types I, II, III)

650-950 nm Pulsed Light attachment:
- ✓ Permanent Hair Reduction (skin type IV)

Comparison: The Synchro HP Platform system has the same indications for use, the same principle of operation, mechanism of action, and very similar performance specifications as the predicate devices.

Nonclinical Performance Data: None

Clinical Performance Data: None

Conclusion: The Synchro HP Platform system is another safe and effective device for the indications specified.

Additional Information: None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 2009

El.En. Electronic Engineering SPA
% Andrea Tozzi
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50041 Calenzano (FI) Italy

Re: K082039
Trade/Device Name: Synchro HP Platform
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 12, 2009
Received: March 16, 2009

Dear Andrea Tozzi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

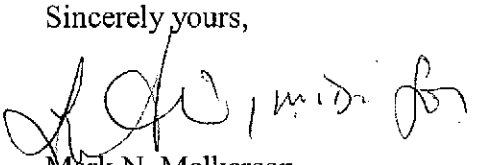
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(K) Number (if known): K082039

Device Name: Synchro HP Platform

Indications For Use:

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Er:YAG Laser attachment (2940 nm): skin resurfacing and incision, excision, ablation or vaporization of soft bodily tissues.

Q-switched Nd:YAG Laser attachment (1064 nm): removal of dark tattoos and treatment of benign pigmented lesions.

Pulsed Light attachments (400, 500, 520, 550, 650 to 950 nm): permanent hair reduction, treatment of benign cutaneous vascular lesions including facial and leg veins, benign pigmented epidermal lesions, moderate inflammatory acne vulgaris.
Different wavelength ranges of Pulsed Light attachments are indicated for the various treatments and skin types, as indicated in the following table:

Pulsed Light wavelength range	Moderate Inflammatory Acne Vulgaris	Benign Cutaneous Vascular Lesions	Benign Pigmented Epidermal Lesions	Permanent Hair Reduction
400 – 950 nm	Skin Types I, II, III, IV	---	---	---
500 – 950 nm	---	Skin Types I, II	---	---
520 – 950 nm	---	Skin Type III	Skin Types I, II	Skin Types I, II
550 – 950 nm	---	---	Skin Types III, IV	Skin Types I, II, III
650 – 950 nm	---	---	---	Skin Type IV

Prescriptive Use ✓ OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE NO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082039